DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Spiriva HandiHaler
Docket No.: 2004E-0304

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

JAN - 6 2006

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,610,163, filed by Boehringer Ingelheim Corporation, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Spiriva HandiHaler, the human drug product claimed by the patent.

The total length of the regulatory review period for Spiriva HandiHaler is 3,318 days. Of this time, 2,557 days occurred during the testing phase and 761 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 1, 1995.

   The applicant claims February 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 1, 1995, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 31, 2001.

   FDA has verified the applicant's claim that the new drug application (NDA) for Spiriva HandiHaler (NDA 21-395) was initially submitted on December 31, 2001.

3. The date the application was approved: January 30, 2004.

   FDA has verified the applicant's claim that NDA 21-395 was approved on January 30, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Michael P. Morris
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